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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/657,404 09/08/2000 Weimin Sun 279.279US1 3413 01/29/2004 **EXAMINER** 21186 SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. OROPEZA, FRANCES P P.O. BOX 2938 ART UNIT PAPER NUMBER MINNEAPOLIS, MN 55402 3762 15

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<del></del>		Application	n No.	Applicant(s)	
		09/657,404	4	SUN ET AL.	CA
Office Action Summary		Examiner		Art Unit	
		Frances P.	Oropeza	3762	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address					
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status					
1)⊠ Responsive to communication(s) filed on 11/10/03 (RCE).					
•	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.				
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims					
4)🖂	)⊠ Claim(s) <u>1-25</u> is/are pending in the application.				
-	4a) Of the above claim(s) is/are withdrawn from consideration.				
5)	Claim(s) is/are allowed.				
	Claim(s) <u>1-25</u> is/are rejected.				
•	Claim(s) is/are objected to.				
8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
9) The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. §§ 119 and 120					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) All b) Some * c) None of:					
<ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> </ol>					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.					
13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)					
since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.					
a) The translation of the foreign language provisional application has been received.					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.					
Attachment(s)					
1) Notic	ce of References Cited (PTO-892)		4) Interview Summary		
$\cdot =$	ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	114.	5) Notice of Informal P 6) Other:	atent Application (PT0	D-152)
a) The second and a second and the second as					

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#### DETAILED ACTION

### Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 11/10/03 has been entered.

## Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kay et al. (US 6411850) in view of Soucie et al. (Article).

Kay et al. disclose a method for automatically determining an anaerobic breakpoint for an adaptive rate pacemaker and for automatically adjusting the pacing rate based on the slope of the rate responsive curve. The cardiac pacemaker pacing signal is modified by the sensed ventilation and the pacing rate is modified in response to ventilatory breakpoint. The control circuit matches the peak ventilation with the maximum pacing rate (col. 3 @ 13-30). Once the breakpoint is reached, the pulse is attenuated based on the rate response slope (col. 5 @ 10-44; col. 7 @ 20-37; figure 1). The dual slope curve of the respiratory rate (figure 1) and the breakpoint, read as the MSR, can be determined from data collected over a period of time to define the respiratory reserve by measuring ventilation during exercise (col. 2 @ 48-65; col. 7 @ 20-24). The breakpoint and curve can also be determined using a pacemaker programmed to determine the ventilatory threshold and peak ventilation which then matches the peak ventilation to the maximal pacing rate (col. 7 @ 1-10). Short-term average relative minute ventilation, 30 second, and long-term average relative minute ventilation, 2 hour, are used to regulate the sensor rate in correspondence to metabolic demand using a Response Factor (col. 8 @ 22-42). The Response Factor slope, which maps the patient's respiratory reserve, is dynamically adjusted based on the maximum daily sensor rate excursions and a weekly average of these readings as compared to a programmed sensor rate (col. 8 @ 43-61). Historically, a fixed percentage of the respiratory reserve is noted as a means used to adjust the pacing rate (col. 8 @ 54-57).

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As discussed in the previous paragraph of this action, Kay et al. disclose comparison of the heart rate to a programmed sensor rate (col. 8 @ 49), but does not identify this rate as the physiologically favorable maximum rate MAR, as claimed in the instant invention.

Soucie et al. teach rate adaptive pacing using a MAR to map a physiologically favorable rate for the purpose of predicting the slope and high rate pacing value. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a MAR to map a physiologically favorable rate in the Kay et al. system in order to use a proven metric enabling effective programming of the rate responsive pacemaker (page 1915, Correlation of S1 with Clinical Parameters; page 1917, Conclusions).

#### Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza Patent Examiner Art Unit 3762 390 1/23/04

AMMELA D. SYKES
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LILLIUGGY CENTER 3700